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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Manabu Komatsu

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EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,660	Applicant(s) KOMATSU ET AL.	
	Examiner Brian R. Gordon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-15-09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-8 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-7, and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 15, 2009 have been fully considered but they are not persuasive. Applicant states "Becker fails to disclose or suggest a chip on which a substance is deposited at plural positions in an amount, at each position, which is an integer multiple of a predetermined amount (existence quantity unit)." It should be noted that applicant's argument is directed to the amount of substance located at each position. Applicant has chosen to refer to the amount at each position as an "existence quantity unit". This "unit" is not generally recognized unit of measurement for volume, mass, weight, density, concentration or any other known defined unit. Applicant's specification at page 9 defines existence quantity unit as the quantity of the chemical substance existing in the respective position." An integer is any positive or negative whole number and the neutral number 0. Therefore, whatever amount of a substance that is present (or absent when 0 is the integer) at a location is the existing quantity. As long as the amount is not a fractional (decimal) amount of the recognizable, known measuring unit then it meets the limitation of the claim. As stated above 0 is an integer therefore the absence of a substance at each of the locations would meet the limitations of the claim.

Applicant further asserts Becker does not disclose how the concentrations of reactive substances differ from one position to the next. In fact, Becker fails to disclose or suggest a method by which the claimed structure can be formed...." These arguments are not commensurate in scope with that of the claims. None of the claims mention "concentration" or any measuring unit thereof. Furthermore none of the claims

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are direct to a method of fabrication, manufacturing, producing, making, etc. the a test specimen as recited in claim 1.

Election/Restrictions

2. Newly submitted claim 8 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 8 is directed to a different species of the one or more chemical substances that was not previously examined. Had the claims being presented as such in the original application a species election would have been required.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 8 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear what structural limitation is intended by the phrase “integer multiples of existence quantity units”. The claim does not specify a recognized unit of measurement for volume, mass, weight, etc. Therefore, one cannot access if an integer multiple is present or not. For example, if the substance is measured in kilograms then

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one could make a determination that 91 grams is not an integer multiple of kilograms, but a fraction thereof. However if the base unit is grams, then 91 grams would be considered an integer multiple.

Becker clearly discloses depositing and maintaining reaction/chemical substances at target sites (different independent positions). The amount maintained at such locations can be various amounts (such as 5, microliters, 200 nanoliters, etc.) that are maintained via a computer system.

Spotting slides, arraying substrates, chemical libraries, assay microchips, etc. and other testing devices of the like are conventionally known in the art and simply varying the amount of indicator, binding, reagent, or testing agent at different spotting locations is not novel within the art. Varying the amount of reactive components only requires routine skill in the art for achieving the optimum, workable ranges for efficient use of such material.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 6-7, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Becker et al. US 6,485,913.

Becker et al. discloses a solid support useful in an open system for maintaining a volume of a liquid at a predetermined volume can be constructed of any material having a surface, which can be flat or geometrically altered, for example, to include wells. The solid support is any known to those of skill in the art as matrix for performing synthetic reactions and assays. It can be fabricated from silicon, glass, silicon-coated materials, metal, a composite, a polymeric material such as a plastic, a polymer-grafted material, such as a metal-grafted polymer, or other material as disclosed herein. This material can be further functionalized, as necessary, for example, chemically, to enhance or permit linkage of molecules or other particles, such as cells or cell membranes or viral

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envelopes or other such biological materials, of interest. The surface of a support can be modified, such as by radiation grafting of a suitable polymer on the surface and derivatization thereof to render it suitable for binding capturing a molecule or particle, such as a cell. (column 15, lines 23-40).

A liquid dispensing system can include a single fluid transmitting vesicle or multiple vesicles, which can be manipulated independently or together in parallel. A fluid transmitting vesicle can be a solid vesicle, to which the liquid can adsorb and be transferred, or can have a bore, through which the liquid is transferred. Thus, a fluid transmitting vesicle can be a pipet, particularly a micropipet, which contains a chamber for holding or transferring the liquid and an end from which the liquid can be dispensed to a target site; a pin tool, which can have a bore, or can be solid vesicle, which, when dipped into a chamber holding a liquid, adsorbs a volume of the liquid, which then can be transferred to a target site; or a liquid sonicating, vaporizing or ink jet device, which contains a chamber for holding the liquid, and an end from which the liquid is dispensed in droplets, the volume and rate of dispensing of which can be adjusted as desired.(column 21, lines 33-59).

A biopolymer sequencing reaction such as the Maxam-Gilbert method or Sanger-Coulson method conveniently can be performed, for example, on a microchip, in which a number of reactions, including the four (or five) base specific reaction, can be performed in parallel on one or more polynucleotides, or a single base reaction can be performed on a number of different polynucleotide sequences. Such methods of polynucleotide sequencing result in the production of nested fragments of the polynucleotide, which can

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be detected using various methods, particularly mass spectrometry, including matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry or capillary electrophoresis. (column 29, lines 26-33 and column 23, lines 22-25).

Becker et al. does not disclose the binding agent is an integer multiple, however the claims do not require the presence or absence of a specific substance, therefore the absence of any binding substance on the substrate (where the integer is 0) meets. The limitation as claimed.

Furthermore as stated above, spotting slides, arraying substrates, chemical libraries, assay microchips, etc. and other testing devices of the like are conventionally known in the art and simply varying the amount of indicator, binding, reagent, or testing agent at different spotting locations is not novel within the art. Varying the amount of reactive components only requires routine skill in the art for achieving the optimum, workable ranges for efficient use of such material.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
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